

(2) When the Secretary's decision is adverse to an enrollee due to an enrollee's failure to submit proof in conformity with a regulation prescribed under section 205(a) of the Act pertaining to the type of proof an enrollee must offer to establish entitlement to payment, the court will review only whether the proof conforms with the regulation and the validity of the regulation.

**§ 423.2138 Case remanded by a Federal District Court.**

When a Federal District Court remands a case to the Secretary for further consideration, unless the court order specifies otherwise, the MAC, acting on behalf of the Secretary, may make a decision, or it may remand the case to an ALJ with instructions to take action and either issue a decision, take other action, or return the case to the MAC with a recommended decision. If the MAC remands a case, the procedures specified in § 423.2140 will be followed.

**§ 423.2140 MAC Review of ALJ decision in a case remanded by a Federal District Court.**

(a) *General rules.* (1) In accordance with § 423.2138, when a case is remanded by a Federal District Court for further consideration and the MAC remands the case to an ALJ, a decision subsequently issued by the ALJ becomes the final decision of the Secretary unless the MAC assumes jurisdiction.

(2) The MAC may assume jurisdiction based on written exceptions to the decision of the ALJ that an enrollee files with the MAC or based on its authority under paragraph (c) of this section.

(3) The MAC either makes a new, independent decision based on the entire record that will be the final decision of the Secretary after remand, or remands the case to an ALJ for further proceedings.

(b) *An enrollee files exceptions disagreeing with the decision of the ALJ.* (1) If an enrollee disagrees with an ALJ decision described in paragraph (a) of this section, in whole or in part, he or she may file exceptions to the decision with the MAC.

(2) Exceptions may be filed by submitting a written statement to the

MAC setting forth the reasons for disagreeing with the decision of the ALJ.

(i) The enrollee must file exceptions within 30 calendar days of the date the enrollee receives the decision of the ALJ or submit a written request for an extension within the 30 calendar day period.

(ii) The MAC will grant a timely request for a 30 calendar day extension. A request for an extension of more than 30 calendar days must include a statement of reasons as to why the enrollee needs the additional time and may be granted if the MAC finds good cause under the standard established in §§ 405.942(b)(2) or (b)(3) of this chapter.

(3) If written exceptions are timely filed, the MAC considers the enrollee's reasons for disagreeing with the decision of the ALJ. If the MAC concludes that there is no reason to change the decision of the ALJ, it will issue a notice addressing the exceptions and explaining why no change in the decision of the ALJ is warranted. In this instance, the decision of the ALJ is the final decision of the Secretary after remand.

(4) When an enrollee files written exceptions to the decision of the ALJ, the MAC may assume jurisdiction at any time. If the MAC assumes jurisdiction, it makes a new, independent decision based on its consideration of the entire record adopting, modifying, or reversing the decision of the ALJ or remanding the case to an ALJ for further proceedings, including a new decision. The new decision of the MAC is the final decision of the Secretary after remand.

(c) *MAC assumes jurisdiction without exceptions being filed.* (1) Any time within 60 calendar days after the date of the written decision of the ALJ, the MAC may decide to assume jurisdiction of the case even though no written exceptions have been filed.

(2) Notice of this action is mailed to the enrollee at his or her last known address.

(3) The enrollee will be provided with the opportunity to file a brief or other written statement with the MAC about the facts and law relevant to the case.

(4) After the brief or other written statement is received or the time allowed (usually 30 calendar days) for submitting them has expired, the MAC

will either issue a final decision of the Secretary affirming, modifying, or reversing the decision of the ALJ, or remand the case to an ALJ for further proceedings, including a new decision.

(d) *Exceptions are not filed and the MAC does not otherwise assume jurisdiction.* If no exceptions are filed and the MAC does not assume jurisdiction over the case within 60 calendar days after the date of the ALJ's written decision, the decision of the ALJ becomes the final decision of the Secretary after remand.

### Subpart V—Part D Marketing Requirements

SOURCE: 73 FR 54222, Sept. 18, 2008, unless otherwise note.

#### § 423.2260 Definitions concerning marketing materials.

As used in this subpart—

*Marketing materials.* Marketing Materials include any informational materials targeted to Medicare beneficiaries which—

- (1) Promote the Part D plan.
- (2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in a Part D plan.
- (3) Explain the benefits of enrollment in a Part D plan, or rules that apply to enrollees.
- (4) Explain how Medicare services are covered under a Part D plan, including conditions that apply to such coverage.
- (5) May include, but are not limited to—
  - (i) General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet.
  - (ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.
  - (iii) Presentation materials such as slides and charts.
  - (iv) Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers).
  - (v) Membership communication materials such as membership rules, subscriber agreements, member handbooks

and wallet card instructions to enrollees.

(vi) Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.

(vii) Membership activities (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or nonclaim-specific notification information).

(6) Marketing materials exclude ad hoc enrollee communications materials, meaning informational materials that—

- (i) Are targeted to current enrollees;
- (ii) Are customized or limited to a subset of enrollees or apply to a specific situation;
- (iii) Do not include information about the plan's benefit structure; and
- (iv) Apply to a specific situation or cover member-specific claims processing or other operational issues.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19825, Apr. 15, 2010]

#### § 423.2262 Review and distribution of marketing materials.

(a) *CMS review of marketing materials.*

(1) Except as provided in paragraph (a)(2) of this section, a Part D plan may not distribute any marketing materials (as defined in § 423.2260 of this Part), or enrollment forms, or make such materials or forms available to Part D eligible individuals unless—

(i) At least 45 days (or 10 days if using certain types of marketing materials that use, without modification, proposed model language and format, including standardized language and formatting, as specified by CMS) before the date of distribution, the Part D sponsor submits the material or form to CMS for review under the guidelines in § 423.2264 of this subpart; and

(ii) CMS does not disapprove the distribution of new material or form.

(2) [Reserved]

(b) *File and use.* The Part D sponsor may distribute certain types of marketing material, designated by CMS, 5 days following their submission to CMS if the Part D sponsor certifies that in the case of these marketing materials, it followed all applicable